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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,332	11/20/2003	Sean A. McCarthy	1855.2058-001	3405

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,332	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-7 (each in part), 12 (in part) and 26, drawn to nucleic acids encoding SEQ ID NO: 2 (such as SEQ ID NO: 1), generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.
2. Claims 1-7 (each in part), 12 (in part) and 27, drawn to nucleic acids encoding SEQ ID NO: 4 (such as SEQ ID NO: 3); generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.
3. Claims 1-7 (each in part), 12 (in part) and 28, drawn to nucleic acids encoding SEQ ID NO: 6 (such as SEQ ID NO: 5), generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.
4. Claims 1-7 (each in part), 12 (in part) and 29, drawn to nucleic acids encoding SEQ ID NO: 10 (such as SEQ ID NO: 9); generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.
5. Claims 1-7 (each in part), 12 (in part) and 30, drawn to nucleic acids encoding SEQ ID NO: 12 (such as SEQ ID NO: 11), generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.

6. Claims 1-7 (each in part), 12 (in part) and 31, drawn to nucleic acids encoding SEQ ID NO: 14 (such as SEQ ID NO: 13), generic fragments and allelic variants thereof, vectors comprising same, host cells comprising same, and methods of recombinantly expressing the encoded polypeptides, classified in class 435, subclass 69.1, for example.

7. Claims 8-10 (each in part) and 32, drawn to polypeptides comprising SEQ ID NO: 2, and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

8. Claims 8-10 (each in part) and 33, drawn to polypeptides comprising SEQ ID NO: 4., and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

9. Claims 8-10 (each in part) and 34, drawn to polypeptides comprising SEQ ID NO: 6*, and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

10. Claims 8-10 (each in part) and 35, drawn to polypeptides comprising SEQ ID NO: 10., and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

11. Claims 8-10 (each in part) and 36, drawn to polypeptides comprising SEQ ID NO: 12., and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

12. Claims 8-10 (each in part) and 37, drawn to polypeptides comprising SEQ ID NO: 14., and generic fragments and variants thereof, classified in class 530, subclass 350, for example.

13. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 2, and methods of making and using same, classified in class 530, subclass 387.1 , for example.

14. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 4, and methods of making and using same, classified in class 530, subclass 387.1 , for example.

15. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 6, and methods of making and using same, classified in class 530, subclass 387.1 , for example.

16. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 10, and methods of making and using same, classified in class 530, subclass 387.1, for example.

17. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 12, and methods of making and using same, classified in class 530, subclass 387.1, for example.

18. Claims 11, 13-15 and 23-25 (each in part), drawn to antibodies that bind SEQ ID NO: 14, and methods of making and using same, classified in class 530, subclass 387.1, for example.

19. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 2 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

20. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 4 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

21. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 6 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

22. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 10 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

23. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 12 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

24. Claims 16 and 17 (each in part), drawn to methods of detecting nucleic acids encoding SEQ ID NO: 14 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, comprising contacting a sample with a nucleic acid probe and determining binding, classified in class 435, subclass 6, for example.

25. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 2 (such as SEQ ID NO: 1) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

26. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 4 (such as SEQ ID NO: 3) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

27. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 6 (such as SEQ ID NO: 5) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

28. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 10 (such as SEQ ID NO: 9) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

29. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 12 (such as SEQ ID NO: 11) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

30. Claim 18 (in part), drawn to kits comprising a compound which selectively hybridizes with nucleic acids encoding SEQ ID NO: 14 (such as SEQ ID NO: 13) or generic fragments or allelic variants thereof, classification dependent upon structure of compound.

31. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 2 or generic fragments or variants thereof, classification dependent upon structure of compound.

32. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 4 or generic fragments or variants thereof, classification dependent upon structure of compound.

33. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 6 or generic fragments or variants thereof, classification dependent upon structure of compound.

34. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 10 or generic fragments or variants thereof, classification dependent upon structure of compound.

35. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 12 or generic fragments or variants thereof, classification dependent upon structure of compound.

36. Claims 19, 20 and 22 (each in part), drawn to methods of identifying compounds that bind or modulate the activity of a polypeptide comprising SEQ ID NO: 14 or generic fragments or variants thereof, classification dependent upon structure of compound.

37. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 2 or generic fragments or variants thereof, classification dependent upon structure of compound.

38. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 4 or generic fragments or variants thereof, classification dependent upon structure of compound.

39. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 6 or generic fragments or variants thereof, classification dependent upon structure of compound.

40. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 10 or generic fragments or variants thereof, classification dependent upon structure of compound.

41. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 12 or generic fragments or variants thereof, classification dependent upon structure of compound.

42. Claim 21 (in part), drawn to methods of modulating the activity of a polypeptide comprising SEQ ID NO: 14 or generic fragments or variants thereof, classification dependent upon structure of compound.

The inventions are distinct, each from the other because of the following reasons:

Each of the following collections of Inventions differ only by the sequence of the recited polypeptide of nucleic acid molecule: 1-6, 7-12, 13-18, 19-24, 25-30, 31-36, and 37-42. A search of any one of the Inventions requires a search of the sequence and literature databases for the sequence recited in the claims. For example, a search for SEQ ID NO: 2 would not provide results relevant for SE QID NO: 12. The searches would not be co-extensive. Therefore, a search

and examination of each collection of Inventions as one Invention would result in an undue search burden for the examiner.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. j 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. The nucleic acids of Inventions 1-6, the corresponding polypeptides of Inventions 7-12, the corresponding antibodies of Inventions 13-18, and the corresponding kits of Inventions 25-30 are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the proteins of Inventions 7-12 can be prepared by processes which are materially different from recombinant DNA expression of Inventions 1-6, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNAS of Inventions 1-6 can be used other than to make the proteins of Inventions 7-12, such in gene therapy or as a probe in nucleic acid hybridization assays. The proteins of Inventions 7-12 can be used in materially different methods other than to make the antibodies of Inventions 13-18, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibodies of Inventions 13-18 can be used to obtain the DNAS of Inventions 1-6, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The kits of Inventions 25-30 are independent and distinct from the nucleic acids of Inventions 1-6, because the kits are not required to contain nucleic acid compounds. The kits of Inventions 25-30 are independent and distinct from the proteins of Inventions 7-12, because the kits are not required to contain protein compounds. Finally, the kits of Inventions 25-30 are

independent and distinct from the antibodies of Inventions 13-18, because the kits are not required to contain antibody compounds. Therefore, search and consideration of all four types of products in one patent application would result in an undue burden on the examiner, especially because the searches required are not co-extensive.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. b 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: The methods of Inventions 19-24, 31-36 and 37-42 are directed to methods that are distinct both physically and functionally, and are not required one for the other. Inventions 19-24 require search and consideration of nucleic acid hybridization, which is not required by any of the other groups. Inventions 31-36 require measurement of the effects of a candidate compound on protein binding or activity, which is not required by any of the other groups. Inventions 37-42 require search and consideration of modulating protein activity, which is not required by any of the other groups. Therefore, a search and examination of all three methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

The following pairs of Inventions are related as product and process of use: 1/19; 2/20; 3/21; 4/22; 5/23; and 6/24. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids

of each pair can be used in methods which do not involve hybridization, such as in recombinant methods of producing the encoded proteins.

The following pairs of Inventions are related as product and process of use: 7/31; 8/32; 9/33; 10/34; 1 1/35; and 12/36. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of each pair can be used in methods which do not involve identification of binders or modulators, such as in protein therapy methods.

The following pairs of Inventions are related as product and process of use: 7/37; 8/38; 9/39; 10/40; 11/41; and 12/42. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of each pair can be used in methods which do not involve activity modulation, such as in receptor isolation.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of each remaining invention pair is not required by the method of the invention pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER